UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

SW

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,575	04/14/2000	FRANCIS JAMES ROURKE	7042-R	9622

27752 7590 12/23/2004

THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
WINTON HILL TECHNICAL CENTER - BOX 161
6110 CENTER HILL AVENUE
CINCINNATI, OH 45224

EXAMINER	
ANDERSON, CATHARINE L	
ART UNIT	**PAPER NUMBER**
3761	

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/529,575	ROURKE ET AL.	
	Examiner	Art Unit	
	C. Lynne Anderson	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,32,36,41-46 and 48-53* is/are rejected.

7)☒ Claim(s) *42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 42 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 42 depends from claim 41, which in turn depends from claim 31. Claim 31 discloses an absorbent article comprising from 0.0001% to 30% by weight of a protease inhibitor. Claim 41 further limits the absorbent article to comprise a delivery system, the delivery system comprising the protease inhibitor. Claim 41 does not require any further components to the absorbent article, and it is within the scope of claim 41 that the absorbent article is the delivery system. Claim 42 further limits the delivery system as being a skin care composition. Therefore, if the absorbent article is the delivery system, and the delivery system is a skin care composition, the absorbent article is the skin care composition. Since claim 42 discloses the skin care composition comprises from 0.01% to 50% by weight of the protease inhibitor, claim 42 fails to further limit claim 31, and in fact broadens the scope of claim 31.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 31, 32, 36, 41-46, and 48-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cadwell (5,874,164).

With respect to claims 31, 32, and 36, Cadwell discloses all aspects of the claimed invention but remains silent as to the percent by weight of the protease inhibitor. Cadwell discloses an absorbent article, as described in column 6, lines 23-26, at least a portion of which comprises a protease inhibitor, as described in column 55, lines 16-19. The protease inhibitor is pentamidine, as described in column 55, line 28.

It would have been obvious to one of ordinary skill in the art at the time of invention to have the protease inhibitor present in the article in a range of about 0.0001% to about 30% by weight. The protease inhibitor of Cadwell is coated onto the absorbent article, as disclosed in column 56, lines 15-21, and to coat the surface of the article fully, the amount of protease inhibitor would obviously have to be greater than 0.0001% by weight. However, the surface of the article can only accommodate so much of a coating, and therefore it would also be obvious that the protease inhibitor would not be greater than 30% by weight.

The IC_{50} is defined in the instant specification on page 7 as being dependant on the concentration of protease inhibitor and the rate of substrate cleavage of the protease inhibitor. The rate of substrate cleavage is dependent on the individual protease inhibitor, and pentamidine is disclosed in the specification as being a suitable protease inhibitor. Therefore, pentamidine, when present in the claimed concentration, inherently has an IC_{50} of about 500

μM or less, no more than 100 μM, and as a result is capable of producing at least a 10% reduction in substrate hydrolysis by a protease.

With respect to claim 41, the article comprises a delivery system, a barrier web 15, as shown in figure 8, which comprises the protease inhibitor.

With respect to claims 42 and 43, the article can comprise a delivery system, a bandage or surgical gauze, as disclosed in column 53, lines 57-62, which facilitates the healing of a wounds and is therefore a skin care composition. The skin care composition comprises between about 0.0001% and about 30% of the protease inhibitor, as disclosed in the rejection of claim 31 above.

With respect to claim 44, the delivery system is a solid support.

With respect to claim 45, the delivery system in activatable by moisture and releases the protease inhibitor, as disclosed in column 55, lines 31-35.

With respect to claim 46, the deliver system contains the protease inhibitor as molecules, or particles, as disclosed in column 55, line 37.

With respect to claim 48, the article comprises a barrier web 15, as shown in figure 8, having the protease inhibitor disposed on at least a portion thereof. The barrier web 15 comes in contact with the wearer.

With respect to claim 49, the barrier web 15 is part of the waist region of the article, as shown in figure 7.

With respect to claims 50 and 51, the wearer-contacting surface may be a bandage or surgical gauze, as disclosed in column 53, lines 57-62, which is a topsheet.

With respect to claims 52 and 53, it would have been an obvious matter of design choice for the topsheet to comprise regions that do not contain the skin care composition and have the skin care composition disposed in a plurality of stripes, since the applicant has not shown that this application of the skin care composition solves any stated problem or serves any particular purpose, and it appears the invention would perform equally well with the skin care composition disposed on all regions of the topsheet. *In re Dailey*, 140 USPQ 47.

Response to Arguments

Applicant's arguments filed 12 October 2004 have been fully considered but they are not persuasive.

In response to the applicant's argument that the claims are not obvious since there is no express disclosure by Caldwell of the claimed range amount of pentamidine, it is noted that it is due to the lack of an express disclosure of the amount of pentamidine that Caldwell is applied under 35 U.S.C. 103(a). Caldwell need not teach that pentamidine is a "results-effective variable," since the rejection is based on the obviousness of a coating on an absorbent article to comprise more than 0.0001% but less than 30% of the total weight of the article. With respect to the upper limit of the range, a coating on the barrier layer of an absorbent article would obviously not comprise such a large portion of the article, since the coating will only comprise a thin layer covering the surface area of the barrier layer. Likewise, it would be obvious that a coating on the barrier layer of an absorbent article would comprise enough material to be at least the very low

amount of 0.0001% by weight, since the coating covers the entire surface area of the barrier layer. Therefore, Caldwell obviously teaches the claimed invention.

In response to the applicant's argument that inherency has no place in the determination of obviousness, it is noted that it is the amount of pentamidine that is obvious, not the IC_{50} of the pentamidine. The IC_{50} is a value inherent to the compound for a given concentration. Therefore, the article of Caldwell, as obviously modified to comprise pentamidine in the claimed amount, will inherently have an IC_{50} in the claimed range.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Lynne Anderson whose telephone number

is (571) 272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Schwartz can be reached on (571) 272-4390. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CWA
cla
December 21, 2004

Larry I. Schwartz
Supervisory Patent Examiner
Group 3700